

REMARKS

I. Summary of the Office Action Mailed April 30, 2007

In the Office Action mailed September 21, 2007, the Office restated the previous Objection to the Drawings. Further, the Office rejected claims 1-10 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,716,638 (Touitou) in view of U.S. Patent No. 6,509,005 (Peart) and "*Airways Response to Aerosolized Delta-9-Tetrahydrocannabinol: Preliminary Report*" by Vachon *et al.* (Vachon). Further, the Office rejected claims 9-10 under 35 U.S.C. § 103(a) as being unpatentable over Touitou in view of Peart and Vachon, and further in view of U.S. Patent No. 5,258,336 (LaMastro).

II. Status of the Claims

Claims 1-10 are currently pending. Claims 1, 6 and 7 have been amended. No new matter is presented by these amendments. Support for the amendments can be found at least at paragraphs 50-58 of the published application.

III. Response to the Rejections

- A. *Claims 1-10 Are Not Obvious Under 35 U.S.C. § 103(a) Over Touitou In View of Peart and Vachon.*

Touitou, either alone or in combination with Peart and Vachon fails to teach or suggest all of the elements of the pending claims. Touitou discloses a cosmetic or medical composition containing an active for topical administration. (Touitou at abstract.) The topical delivery system disclosed therein contains phospholipids, short chain alcohols and water that may also comprise a glycol and incorporates the active by forming ethosomal emulsion. (Touitou 1:8-11.) Notably, Touitou relies on the presence of a phospholipid in order to stabilize the disclosed emulsion. In fact, nowhere within Touitou is an embodiment disclosed which does not contain a phospholipid. As such, the presence of a phospholipid is a necessary element of Touitou. Additionally, Touitou specifically states that its solvent system requires "relatively high concentration" of either ethanol alone or ethanol in combination with a glycol. (Touitou at 4:22-24).

Touitou teachings fail to teach or suggest all of the limitations of the claims as amended. The disclosures in Touitou regarding an emulsion-stabilized topical delivery system fail to provide any guidance to one skilled in the art regarding the development of the semiaqueous aerosol system as disclosed in the application. To the extent Touitou provides generalized

teachings regarding the solubilized tetrahydrocannabinol ("THC"), it relies entirely on the formation of emulsion necessarily containing a phospholipid. In contrast, the application discloses a semiaqueous solvent system that, by definition does not rely on the formation of an emulsion.

The teachings of Peart fail to remedy the deficiencies of Touitou. Peart discloses an aerosol propellant system for THC that does not require the presence of a solvent. (Peart at 5:50-55.) Peart further discloses that if a solvent, such as ethanol is used, it should comprise less than 20%, and most preferably, less than 15% of the system. (Peart at 5:52-55.) Moreover, Peart teaches away from the use concentrations of ethanol larger than about 20% when administering THC to the lungs because the resulting droplet size will be too large to be effectively inhaled. (Peart at 5:28-32.) Thus, Peart teaches a composition that relies upon low concentrations of alcohol, and specifically criticizes and discourages the use of higher concentrations of alcohol.

In contrast to the teaching of Peart, the amended claims now require that the concentration of ethanol be in excess of 20% of the composition. This limitation is in direct opposition to the teachings of Peart that ethanol concentrations in excess of 20% will result in a droplet size too large to be absorbed via inhalation.

Similarly, the disclosures in Vachon provide no improvement on the shortcomings of Touitou in regard to the present invention. Vachon discloses a solvent system for aerosol delivery of THC comprising a ratio of propylene glycol to water of 9:1. (Vachon at 112.) These teachings stand in contrast to the claims of the present invention which have been amended to have a propylene glycol in the range of 20-65% of the composition.

Further, a person of skill in the art would find the disclosures in Touitou irrelevant when reading Peart or Vachon. Touitou relies on the formation of phospholipid-based emulsion, while Peart and Vachon rely on organic solvent systems. Said differently, the favorable combination of ethanol and propylene glycol *in a phospholipid emulsion* provides no indication to one skilled in the art that ethanol and propylene glycol could be favorably combined in a semiaqueous solution as disclosed in the application. Peart does not disclose the use of a glycol in this fashion. Vachon does not disclose a system with ethanol. Therefore, neither Peart nor Vachon teach that a combination of ethanol and glycol can be used to solubilize THC for administration to the lungs without the presence of a phospholipid and form an emulsion.

Moreover, the disclosures in Touitou and Peart are contradictory regarding the effect of ethanol on the particle size. While Peart discloses that increasing the alcohol concentration about 20% increases the particle size to the point that aerosol administration is no longer effective, (Peart at 6:16-20), Touitou discloses that high alcoholic concentration favors the production of *smaller sized* particles. (Touitou at 2:26-29.) Based on this discrepancy, one skilled in the art would believe that the effect of increasing alcohol concentrations on particle size in Touitou was related to the emulsion formation. Thus, one skilled in the art would not believe that the same positive effect would occur in a semiaqueous solvent system, which, by definition does not involve the formation of an emulsion.

Based on the foregoing, Applicant respectfully submits that independent Claim 1 is not obvious over Touitou in view of Peart and Vachon. Claims 2 to 10 depend from independent Claim 1. Therefore, the patentability of independent Claim 1, as amended, over the prior art establishes the patentability of Claims 2-10. Therefore, Applicant respectfully requests the rejection under 35 U.S.C. § 103(a) be withdrawn.

B. Claims 9-10 Are Not Obvious Under 35 U.S.C. § 103(a) Over Touitou In View of Peart, Vachon and LaMastro.

The Office rejected Claims 9 and 10 as obvious over Touitou in view of Peart, Vachon and LaMastro. Based on the discussion above, Touitou in view of Peart and Vachon fails to teach or suggest all the elements of Claim 1 as amended. The teachings of LaMastro do not remedy the deficiencies in the teachings of Touitou, Peart and Vachon regarding Claim 1, as the teaching of LaMastro are directed toward the stability of compounds in amber bottles. Claims 9 and 10 depend from independent Claim 1. Therefore, the patentability of independent Claim 1, as amended, over the prior art establishes the patentability of claims 9-10. Therefore, Applicant respectfully requests the rejection under 35 U.S.C. § 103(a) be withdrawn.

IV. Conclusion

All objections and rejections having been traversed, Applicant submits that all claims are in condition for allowance and respectfully requests notice to that effect. Should the Examiner wish to discuss the case with the undersigned, the Examiner is invited to call the undersigned at 312-701-8979.

Respectfully submitted,

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